



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Draft Report entitled "EPA Deviated from Typical Procedures in its 2018 Dicamba Pesticide Registration Decision."

FROM: Michal Freedhoff, Ph.D.
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

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TO: Sean O'Donnell
Inspector General

This memorandum responds to the Draft Report of the Office of Inspector General (OIG) entitled "EPA Deviated from Typical Procedures in its 2018 Dicamba Pesticide Registration Decision," Project No. OA&E-FY20-0122, dated March 29, 2021.

I. General Comments:

The Office of Chemical Safety and Pollution Prevention (OCSPP) very much appreciates the OIG's effort in evaluating the following:

- The effectiveness of the U.S. Environmental Protection Agency's policies and procedures in addressing stakeholder risks in the 2016 and 2018 dicamba pesticide registration decisions.

The Draft Report appropriately observes that OCSPP, when making future pesticide registration decisions, must follow its existing processes and procedures. The long-standing framework for registration decisions cited in the Draft Report is indeed designed to – and as routinely implemented by our career scientists does indeed – ensure that our scientific products are sound and that scientific methods used are transparent and appropriate. This incident occurred despite the best efforts of OCSPP's career scientists and managers to recommend a different approach that was scientifically, procedurally and legally sound.

The Draft Report also states that senior managers – whether policy makers or scientists – must document their changes and record the reasons for them. OCSPP understands the Report as referring to material changes to scientific conclusions or analyses, or how those conclusions are presented. OCSPP also understands the Draft Report to refer to material changes to scientific conclusions or analyses achieved by excluding, including, downplaying or otherwise manipulating key data. A material change is one that affects the scientific content or how it may be understood. OCSPP agrees that documenting such changes is imperative. OCSPP understands the Draft Report *not* to refer to editorial or organizational changes intended to improve the clarity of the document or its ease of use. The Draft Report further notes that changes to scientific conclusions must be based exclusively on scientific (not policy) considerations. Again, OCSPP agrees. Indeed, OCSPP is emphasizing these points to all our managers.

As noted in the Draft Report, training is imperative. Contrary to a finding in the Draft Report, however, OCSPP staff and managers – and the senior leaders involved in the 2018 dicamba decision – *did* receive considerable scientific integrity training over the past four years. Moreover, such training has been required for all employees since 2018. In addition, there was a module specifically designed for supervisors and managers that was administered to all OCSPP leaders in 2018. In fact, EPA’s Scientific Integrity Official, Dr. Francesca Grifo, reports more than 50 training events in OCSPP alone from 2017 to 2020. The dicamba incident described in this Draft Report did not occur due to a lack of awareness of or training on the agency’s Scientific Integrity Policy. It occurred because OCSPP’s past senior leadership consciously chose to advance a policy outcome in a manner inconsistent with the Scientific Integrity Policy.

II. OCSPP’s Response to the Recommendations:

The Draft Report dated March 29, 2021, contains three (3) recommendations for OCSPP’s Office of Pesticide Programs (OPP):

Recommendation 1: Implement a procedure requiring senior managers or policy makers to document changes or alterations to scientific opinions, analyses, and conclusions in interim and final pesticide registration decisions and their bases for such changes or alterations.

- **OCSPP Response:** OCSPP largely agrees with Proposed Recommendation 1, with some clarification. OCSPP agrees that appropriate documentation is imperative. See OCSPP’s explanation below and Proposed Corrective Action 1.
 - First, Proposed Recommendation 1 appears to assume that non-scientist senior managers or policy makers will “change” or “alter” scientific opinions, analyses or conclusions. To so do could violate the Scientific Integrity Policy, even if they did document the change. OCSPP suggests the wording of this recommendation be clarified.
 - Second, OCSPP understands Proposed Recommendation 1 to refer to material changes to scientific conclusions or analyses achieved by excluding, including, downplaying or otherwise manipulating key data. A material change is one that affects the scientific content or how it may be understood. OCSPP agrees that documenting such changes is imperative. OCSPP proposes an alternate Corrective

Action that in our view will accomplish the same goal as Proposed Recommendation 1.

- **Proposed Corrective Action 1:** OCSPP's scientific integrity and quality assurance lead(s) will develop Standard Operating Procedures (SOPs) or formal Best Practices on ensuring scientific integrity in pesticide regulatory decisions. These SOPs will ensure that material changes to the risk assessment, risk characterization, and science documents from outside of the authoring OPP Division are clearly documented and communicated by those making the changes (e.g., by saving as a new EPA record each materially-amended document change, noting the author of each change and in language in redline/strikeout format). A "material change" to a scientific conclusion or analysis is one that affects the scientific content or how it may be understood and/or excludes, includes, downplays or otherwise manipulates key data. The SOPs will also make clear that scientific opinions, analyses, and conclusions may be changed only on scientific, not policy, grounds.
- **Target Completion Date:** CA 1: OCSPP will complete develop Standard Operating Procedures (SOPs) or formal Best Practices on ensuring scientific integrity in pesticide regulatory decisions by March 31, 2022.

Recommendation 2: Require an assistant administrator-level verification statement that Scientific Integrity Policy requirements were reviewed and adhered to during the pesticide registration process.

- **OCSPP Response:** OCSPP agrees in part and disagrees in part with Proposed Recommendation 2. The incidents described in this Draft Report reflected a purposeful decision made by the three senior leaders in OCSPP's immediate office at the time of the 2018 dicamba decision. The incidents did not reflect a failure of OCSPP's processes or typical practices. OCSPP has no reason to believe that a different "verification" requirement would have caused these individuals to make a different decision. Moreover, Proposed Recommendation 2 injects senior (political) leaders into the science review process where, currently, most of OCSPP's typical practices do not include such a role. (Most registration decisions are made at the Branch Chief level or lower.) OCSPP proposes an alternate Corrective Action that OCSPP believes accomplishes the overarching goal: obliging Assistant Administrator-level leaders to commit to adhere to the Scientific Integrity Policy.
- **Proposed Corrective Action 2a - d:** The OCSPP Assistant Administrator shall annually issue a memorandum to all OCSPP staff and management to affirm their own and the Office's commitment to the Scientific Integrity Policy and to establish clear expectations of behavior to uphold scientific integrity. OCSPP political leadership issued the first such memorandum on March 10, 2021. This Corrective Action will be tracked for 4 years, or until 2025.
- **Target Completion Dates:**
 - CA 2a: OCSPP shall issue its second annual memo to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2022.
 - CA 2b: OCSPP shall issue its third annual memo for 2023 to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2023.

- CA 2c: OCSPP shall issue its fourth annual memo for 2024 to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2024.
- CA 2d: OCSPP shall issue its fifth annual memo for 2025 to all OCSPP staff and management affirming the office's commitment to the Scientific Integrity Policy by March 31, 2025.

Recommendation 3: Annually conduct and document training for all staff and senior managers or policy makers to affirm the office's commitment to the *Scientific Integrity Policy* and principles and to promote a culture of scientific integrity.

- **OCSPP Response:** OCSPP agrees with Proposed Recommendation 3 and proposes the following Corrective Actions to implement it.
- **Proposed Corrective Actions 3.1a through e:** The OCSPP Deputy Scientific Official, in consultation with the OCSPP Assistant Administrator and EPA's Scientific Integrity Official, shall provide annual Scientific Integrity training for all staff and senior managers or policy makers to affirm the office's commitment to the Scientific Integrity Policy and to promote sound behaviors essential to scientific integrity. On April 12, 2021, OCSPP conducted a OCSPP Scientific Integrity Town Hall featuring the Administrator, Dr. Grifo, and the OSCPP Principal Deputy Assistant Administrator to emphasize key elements of the Scientific Integrity Policy. In addition, over the next twelve months, OCSPP will conduct the following additional Town Hall-style scientific integrity training sessions for all OCSPP employees, including all political appointees, on the following topics:
 - Overview of EPA's Scientific Integrity Program
 - Understanding and honoring the difference between science and policy (risk assessments and risk management)
 - Tools to address differing scientific opinions
 - Whistleblower protections
 - Technical product clearance process and guidance
 - Use of internal and external peer review

In subsequent years, the training series will address topics of particular significance at the time. This Corrective Action will be tracked for 5 years, or until 2026.

- **Target Completion Dates:**
 - CA 3.1a: OCSPP shall complete the first annual training series by March 31, 2022.
 - CA 3.1b: OCSPP shall complete the second annual training series by March 31, 2023.
 - CA 3.1c: OCSPP shall complete the third annual training series by March 31, 2024.
 - CA 3.1d: OCSPP shall complete the fourth annual training series by March 31, 2025.
 - CA 3.1e: OCSPP shall complete the fifth annual series by March 31, 2026.

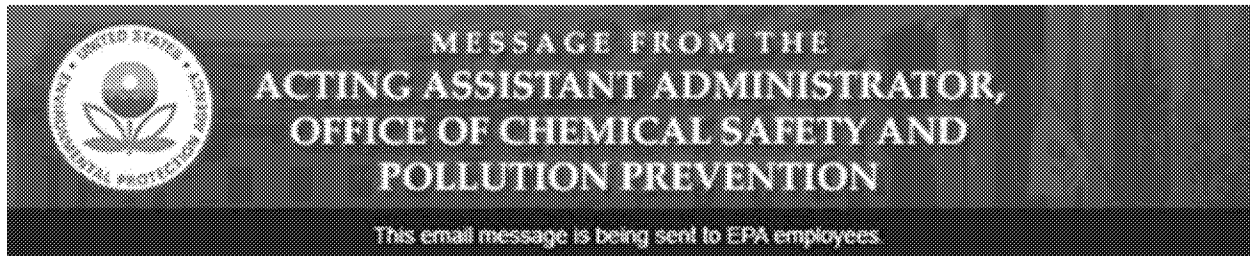
- **Proposed Corrective Action 3.2a – e:** OCSPP shall ensure that all new OCSPP staff and managers, including all political appointees, take the Scientific Integrity Mandatory Training for New Hires within six months of their appointment. This course is designed to increase awareness and understanding of the Agency's Scientific Integrity Policy and demonstrate how scientific integrity enhances the Agency's work. OCSPP will compile an annual report for the Assistant Administrator on organizational compliance with the training requirement by January 31 of each year. This Corrective Action will be tracked for 5 years, or until 2026.
- **Target Completion Dates:**
 - CA 3.2 a: OCSPP will compile its first annual report on organizational compliance with the training requirement by January 31, 2022.
 - CA 3.2 b: OCSPP will compile its second annual report on organizational compliance with the training requirement by January 31, 2023.
 - CA 3.2 c: OCSPP will compile its third annual report on organizational compliance with the training requirement by January 31, 2024.
 - CA 3.2 d: OCSPP will compile its fourth annual report on organizational compliance with the training requirement by January 31, 2025.
 - CA 3.2 e: OCSPP will compile its fifth annual report on organizational compliance with the training requirement by January 31, 2026.

III. Conclusion

OCSPP joins the Office of the Inspector General in affirming the importance of the Scientific Integrity Policy and its emphasis on communication, transparency, and respect for differing scientific opinions. OCSPP welcomes the OIG's efforts to strengthen scientific integrity in OCSPP.

Appendix

[The email below was sent by OCSPP Chief of Staff Tom Tyler on Behalf of Michal Freedhoff on March 10, 2021.]



Dear OCSPP Colleagues – By now, I’ve been a part of the OCSPP team for nearly seven weeks, and I continue to be deeply impressed by and grateful for your integrity, professionalism, and unmatched commitment to public service and the public good.

I have been particularly pleased to see OCSPP career professionals speak strongly in support of Scientific Integrity. As you know, science is the backbone of EPA. Scientific integrity, in turn, is a bedrock principle for President Biden, Vice President Harris, our incoming Administrator Michael Regan, and me. Scientific Integrity ensures that our science is sound and that we earn and maintain the public’s confidence in our decision-making. I affirm my commitment to you to act with scientific integrity. I expect you to do likewise when working with me and with each other.

Our work as a science-based regulatory office requires us to embody scientific integrity in many contexts. For example, I expect:

- Robust exchange of scientific views, with differing scientific opinions expressed in writing early and shared with managers throughout the process, including me.
- Truth-telling in briefings: what do I and other managers need to know?
- Courage to point out errors early in the process and a welcoming attitude by managers and peers to those communications.
- Respect for the role of science in risk assessments and the role of policy and law in risk management decisions. This requires the assurance that risk management considerations aren’t the driving influences during the risk assessment phase, and it requires respect among scientists when difficult policy choices are ultimately made.
- Integrity of scientific products.
- Clear, real-time communication with scientists to explain senior scientists’ changes to draft scientific products and an opportunity for scientists to express a different view.

- Understanding that, as a regulatory office, we also need to be mindful of statutory and other deadlines.
- An environment – led in the first instance by OCSPP managers – where everyone feels comfortable identifying errors, asking questions, and expressing differing scientific opinions, all without fear either of retaliation or being denigrated for speaking up.
- An environment free from political interference in the science.

Over the past few years, I am aware that political interference sometimes compromised the integrity of our science. Here are examples:

2018 Dicamba Registration Decision: In 2018, OCSPP senior leadership directed career staff to: (1) rely on a limited data set of plant effects endpoints; (2) discount specific studies (some with more robust data) used in assessing potential risks and benefits; and (3) discount scientific information on negative impacts. This interference contributed to a court’s vacating registrations based on these and other deficiencies, which in turn impacted growers’ ability to use this product.

TCE: White House staff directed OCSPP career staff to alter the draft TCE risk evaluation to change the point of departure used for making determinations of risk to a less sensitive endpoint. While the risk evaluation included a description of the more sensitive endpoint (fetal heart malformations), it was no longer used to determine whether there is unreasonable risk from TCE. Unreasonable risks were nevertheless identified for most uses of TCE, but the magnitude of the risk from exposures to TCE would have been greater had EPA relied upon the fetal cardiac defect endpoint that had been used in previous EPA peer-reviewed assessments.

PFBS Toxicity Assessment: The PFBS Toxicity Assessment that was recently removed from EPA’s website included conclusions purporting to reflect science when in fact they were the product of biased political interference directed in part by OSCPP’s past political leadership. That interference undermined the agency’s scientific integrity policy and eroded the trust that the American public has in EPA, the quality of our science, and our ability to protect their health and the environment.

This is a new day, about communication, trust, transparency and the importance of science in our regulatory decision-making process. All of us are responsible for ensuring the scientific integrity of our work. All of us are responsible for creating a work environment where everyone feels free to speak up without fear.

To this end, I encourage you to read the [Scientific Integrity Policy](#). I encourage you to browse the Office of Scientific Integrity [Intranet Page](#) and refresh your knowledge by studying their

resources and whiteboards. And please don't hesitate to contact OCSPP's Deputy Scientific Integrity Officer, Carol Ann Siciliano, at siciliano.carolann@epa.gov or (202) 564-5489, or EPA's Scientific Integrity Officer, Francesca Grifo at (202) 564-1687 (office) or (202) 657-8575 (mobile).

I also encourage you to attend the OCSPP Scientific Integrity Training series being launched by Carol Ann. You'll see more information about that shortly. The first session will feature a presentation and Q&A with Francesca Grifo. The second session will talk about ways to express and resolve Differing Scientific Opinions (DSO). Explore the DSO toolkit [here](#). We also plan a training on Whistleblower protections. Get to know your rights [here](#). More training subjects will follow.

Just as important, let's make Scientific Integrity part of our daily work and our daily conversations. You can count on me. And I know that I can count on you – managers and staff, scientists and non-scientists – to do the same.

All the best,
Michal

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